DEC 2 0 2001

K011212

ARC Medical, Inc.
322 Patterson Ave.
Scottsdale, GA 30079

Non-Confidential Summary of Safety and Effectiveness

December 11, 2001

ARC Medical, Inc.
322 Patterson Ave.
Scottsdale, GA 30079

Tel (800) 950-2720
Fax (404) 373-8385

Official Contact: Hal Norris - President

Proprietary or Trade Name: Bact-Trap

Common/Usual Name: Bacterial / Viral Filter

Classification Name: Filter, Bacterial, Breathing Circuit

Predicate Devices: Mallinckrodt HEPA – K941676

Pharma Systems – Bact-Trap – K903056

Device Description:

The Bact-Trap is a bacterial / viral filter designed to be palced in the ventilator or anesthesia breathing circuit. It incorproates standard 15 / 22 mm connectors with a gas sampling port. This device has a dead space of 71 ml and this should be taken into consideration when calculating tidal volume and patient ventilation requirements.

Intended Use:

Indicated Use -- For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and / or expired gases is required. The filter may be positioned at the machine end of the expiratory / inspiratory limb of the circuit, or at the patient end of the circuit.

Environment of Use -- Home, Hospital, Sub-acute Institutions, Emergency services

Comparison to Predicate Devices:

Attribute	Proposed device Bact-Trap	Mallinckrodt HEPA K941676	Pharma Systems Bact-Trap K903056
Intended use	To filter inspired and / or expired gases. The filter may be positioned at the machine end of the expiratory / inspiratory limb of the circuit, or at the patient end of the circuit.	Same	Same

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Attribute	Proposed device Bact-Trap	Mallinckrodt HEPA K941676	Pharma Systems Bact-Trap K903056
Intended for single patient, up to 24 hours	Yes	Yes	Yes
Prescription	Yes	Yes	Yes
Intended population	Adults. Not for neomates or pediatric use at wye because of deadspace. Tidal volume > 300 ml	Same. For patients with Tidal volumes > 150 ml	Same
Intended Environment of Use	Home, Hospital, sub-acute, Emergency services	Same	Same
Placement in various locations in circuit	Yes	Yes	Yes
Design Features			
Various sizes	Yes	Yes	Yes
Gas sampling port	Yes	Yes	Yes
Standard 15/22 mm connectors	Yes	Yes	Yes
Dead Space (ml)	71 ml	92 ml	N/A
Resistance to flow at 60 Lpm	0.95 cm H_2O	1.0 cm H_2O	N/A
Bacterial filtration	99.9999%	99.999999%	N/A
Viral filtration	99.9999%	99.999999%	N/A
Weight	36-40 gm	45 gm	N/A
Materials			
Housing polystyrene	Yes	Yes	Yes
Filter media	Electrostatic polypropylene	Paper fiber	Electrostatic polypropylene
Performance			
None under Section 514	Yes	Yes	Yes
ISO 5356-1 Conical 15/22 mm	Yes	Yes	Yes
ISO 594-2 – Luer fittings	Yes	Yes	Yes

Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the intended device and the predicates – Mallinckrodt – HEPA – K941676 and Pharma Systems Bact-Trap – K903056.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Mr. Hal Norris
ARC Medical, Inc.
322 Patterson Avenue
Scottdale, GA 30079

Re: K011212
Bact – Trap Filter
Regulation Number: 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II (two)
Product Code: 73 CAH
Dated: November 20, 2001
Received: November 21, 2001

Dear Mr. Norris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.3 Indications for Use

510(k) Number: K011212 (To be assigned)

Device Name: Bact-Trap

Intended Use: For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and / or expired gases is required. The filter may be positioned at the machine end of the expiratory / inspiratory limb of the circuit, or at the patient end of the circuit. It should be replaced at least every 24 hours.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011212

Prescription Use √ **or** **Over-the-counter use** __
(Per CFR 801.109)